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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
08 826,361	03/26/1997	SIFSE MOSSELMAN		2161

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EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/17/2002

37

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>08/826,361</b>	Applicant(s) <b>Mosselman et al.</b>
	Examiner <b>Michael Pak</b>	Art Unit <b>1646</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on Mar 27, 2002.
  - 2a)  This action is FINAL.      2b)  This action is non-final.
  - 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4)  Claim(s) 4-7 and 27-34 is/are pending in the application.
  - 4a)  Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
  - 5)  Claim(s) 4-6 and 30 is/are allowed.
  - 6)  Claim(s) 7, 27, 28, and 31-33 is/are rejected.
  - 7)  Claim(s) 29 and 34 is/are objected to.
  - 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO 413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <b>32</b> | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 27 March 2002 (Paper No. 31) has been entered.

***Response to Amendment***

2. Amendments filed 27 March 2002 (Paper No.27) has been entered.

3. Applicant's arguments filed 27 March 2002 have been fully considered but they are not found persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

5. Claims 7, 27, 31 and 32 are rejected under 35 U.S.C. 112,

first paragraph, because the specification, while being enabling for an isolated cell transfected with an expression vector comprising the DNA encoding a protein comprising SEQ ID NO: 5, 6, 21, or 25, does not reasonably provide enablement for a cell transfected with the DNA which is not in an expression vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The reason for the rejection was set forth in the last office action.

Claims 7, 27, 31 and 32 encompass a cell transfected with DNA of claim 1 which is not in a vector. However, the specification does not teach how to transfect cell with DNA which is not in a vector. One of skilled in the art do not transfect cells with cDNA which are not packaged in a vector because without the vector the expression copies of the DNA is not sufficient for expression of the protein product. Applicants argue that page 11 of the specification teaches the techniques for transforming or transfecting host cells are quite known in the art reciting Sambrook et al. However, Sambrook et al do not transform or transfect cells without a vector.

6. Claims 7, 27-28 and 31-33 are rejected under 35 U.S.C. 112,

first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 7, 27, 31 and 32 encompass a cell transfected with DNA which is not in an expression vector. However, the specification does not disclose a cell transfected with DNA which is not in an expression vector. The essential feature of the invention is the cell transfected with DNA which is inside an expression vector. *University of California v. Eli Lilly and Co.* (CAFC) 43 USPQ2d 1398 held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the specification lacks adequate written description for a generic claim to a cell which comprises a DNA which is not in an expression vector.

Claims 7, 28, 31 and 33 encompass a cell which is not isolated from an organism but is transfected with DNA or vector. However, the specification does not disclose a cell transfected with DNA which is in an intact organism. The essential feature of the invention is the cell culture cells transfected with DNA which is inside an expression vector. *University of California v. Eli Lilly and Co.* (CAFC) 43 USPQ2d 1398 held that a generic

claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the specification lacks adequate written description for a generic claim to a cell which comprises a DNA which is not an isolated cell.

7. Claims 4-6 and 30 are allowed. Claims 29 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 5:50 AM to 2:20 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Michael D. Pak*  
Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
12 June 2002